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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,512	06/05/2001	David H. Sachs	59056.__	6693

7590 03/27/2003

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	PAPER NUMBER
1632	5

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/874,512	Sachs
Examiner	**Art Unit**
Anne Marie Wehbé	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 19-23 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 19-23 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's pre-amendments received on 6/5/01 and 9/9/02 have been entered. Claims 1-18 have been canceled and new claims 19-23 have been added. Claims 19-23 are pending in the instant application. An action on the merits follows.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Claims 19-23 recite compositions comprising an anti-CD2 antibody, most specifically the antibody BTI-322, and an immunosuppressive agent. This application is a direct continuation of U.S. Application No. 09/126, 704, which is a direct continuation of U.S. Application No. 08/458,720. The office acknowledges that the both the 09/126, 704 and 09/458,720 provide support for compositions which comprise an anti-CD2 antibody including BTI-322. However, the

applicants have further claimed priority to several parent applications for which the instant application is a continuation in part. None of the specifications of 08/266,427, 08/451,210, 07/838,595, 08/220,371, PCT/US94/05527, 08/243,653, 08/114,072, 08/150,739, 08/212,228, and PCT/US94/01616 provide any support for an anti-**CD2** antibody, or for **BTI-322.** As such, the effective filing date for claims 19-23 is the filing date of the 08/458,720 application, which is June 1, 1995.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19-20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Chavin et al. (1994) Transplantation, Vol. 57, 736-740. The applicant claims a kit comprising an anti-CD2 antibody in a pharmaceutically acceptable carrier and an immunosuppressive agent. The applicant further claims said kit wherein the anti-CD2 antibody is a monoclonal antibody and wherein the immunosuppressive agent is selected from a group consisting of cyclosporine, FK-506, and rapamycin. The applicant has stated that although the specification does not recite such

kits *in haec verba*, the specification discloses combinations of pharmaceutical compositions and agents. Since the word "kit" has not been defined in the specification, the claims have been interpreted according to applicant's description of a combination of an anti-CD2 antibody and an immunosuppressive agent.

Chavin et al. teaches the combined administration of a monoclonal anti-CD2 antibody and an immunosuppressant such as cyclosporine, rapamycin or FK506 in order to increase graft survival in murine cardiac allograft recipients (Chavin et al., page 736, and page 737, Table 1). In particular, Chavin et al. teaches that anti-CD2 monoclonal antibody synergizes with FK506 to induce tolerance to allografts (Chavin et al., page 738, Table 2). Thus, by teaching all the elements of the claims as written, Chavin et al. clearly anticipates the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to

the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/20619 (9/15/94), hereafter referred to as Bazin et al., in view of Chavin et al. (1994) Transplantation, Vol. 57, 736-740. The applicant claims a kit comprising an anti-CD2 antibody in a pharmaceutically acceptable carrier and an immunosuppressive agent. The applicant further claims said kit wherein the anti-CD2 antibody comprises BTI-322 or an antibody which binds an epitope also recognized by BTI-322.

Bazin et al. teaches the inhibition of graft rejection in humans by administration of a monoclonal antibody, LO-CD2a, produced by the cell line ATCC HB 11423 (Bazin et al., abstract, and page 16). Please note that the LO-CD2a antibody is also known in the art as BTI-322. Bazin et al. further teaches the inhibition of graft rejection by administration of an antibody which binds to the same epitope as LO-CD2a (Bazin et al., page 53, claim 26). Bazin et al. differs from the instant invention by failing to teach the combination of the LO-CD2a antibody and an immunosuppressive agent. Chavin et al. supplements Bazin et al. by teaching the combined administration of a monoclonal anti-CD2 antibody and an immunosuppressant such as cyclosporine, rapamycin or FK506 in order to increase graft survival in murine cardiac allograft

recipients (Chavin et al., page 736, and page 737, Table 1). In particular, Chavin et al. teaches that anti-CD2 monoclonal antibody synergizes with FK506 to induce tolerance to allografts (Chavin et al., page 738, Table 2). Since Chavin et al. presents data derived from experiments in mice, the anti-CD2 antibody used in these experiments is an anti-murine CD2 antibody. Based on the motivation provided by Chavin et al. for combining anti-CD2 antibody and FK506 to inhibit graft rejection, it would have been *prima facie* obvious to the skilled artisan to administer FK506 with the LO-CD2a antibody taught by Bazin et al. in order to effect a synergistic increase in tolerance induction in humans with a reasonable expectation of success.

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Fri from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER